REMARKS

Reconsideration of this application is respectfully requested.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-14 and 19-22 was acknowledged by the Office. Applicant argued that it would not have been obvious for someone skilled in the art, who did not know SEQ ID NO: 1, to isolate and to identify the sequence, which hybridizes to SEQ ID NO:1 under stringent conditions. According to the Office, the question of obviousness is irrelevant to the fact that NEB discloses polynucleotides that meet options C and D of the claimed invention. The NEB product is deemed to be composed of every permutation of a 24-mer oligonucleotide, not a universal or degenerate primer. Thus, the restriction requirement was deemed proper and made FINAL. Claims 15-18 and 23-59 were withdrawn from further consideration as being drawn to a nonelected invention. Office Action at 2. Applicant respectfully traverses.

Applicant still maintains that this assertion is hypothetical, since, as stated in response to the restriction requirement, it would not have been obvious for someone skilled in the art, who did not know SEQ ID NO: 1, to isolate and to identify it in view of the NEB sequence. One skilled in the art would not have known any isolated and identified sequence able to hybridize under stringent conditions to sequence SEQ ID NO: 1. Applicant requests that the restriction requirement be reconsidered and withdrawn.

Sequence Rules Compliance

The Office indicated that pages 9 and 36-39, respectively, contain sequences without SEQ ID NOs. The Office indicated that, if these sequences are included in the

sequence listing provided by Applicant, the specification should be amended to include the SEQ ID NOs. If these sequences were not included in the sequence listing, Applicant should provide a substitute sequence listing and a CRF that include those sequences. Office Action at 2-3. This requirement has been addressed and complied with in the accompanying amendment. Thus, the requirement may be withdrawn.

Specification

The disclosure was objected to because it contained an embedded hyperlink and/or other form of browser-executable code on page 22. Applicant was required to delete the embedded hyperlink and/or other form of browser-executable code. Office Action at 4. Appropriate amendments to page 22 have been made. Thus, the objection may be withdrawn.

Claim Objections

Claim 6 was objected to because the word "excepted" should be replaced with "except" to provide for appropriate English grammar. Office Action at 4. Claim 6 has been cancelled. Thus, this objection may be withdrawn.

Claims 9, 14, 19, and 21 were also objected to as being in improper form because a multiple dependent claim cannot depend from any another multiple dependent claim. Office Action at 4. The multiple claim dependency has been amended to conform to U.S. practice. Accordingly, claims 9-14 and 19-22 are in proper form for further consideration on the merits.

Claim Rejections - 35 USC § 112 - Indefiniteness

Claims 3 and 5 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter,

which applicant regards as the invention. These claims were deemed to be indefinite because the scope of the phrase "characterized in that" is unclear. It was suggested that conventional U.S. claim language, such as "comprising," be used in amended claims. Office Action at 5. This ground for rejection has been obviated by the cancellation of claim 3 and the amendment of claim 5 by deleting the expression "characterized in that." Thus, this ground for rejection may be withdrawn.

Claim Rejections - 35 USC § 102

Claims 1-3 and 5-8 were rejected under 35 U.S.C. § 102(b) as being anticipated by Brennan (U.S. 5,474,796). According to the Office, the rejection of claim 6 is further evidenced by GENBANK Accession Number L26330 (uploaded to NCBI June 4,1994) and BLAST search completed @ NCBI on August 13, 2008.

With regard to claims 1-3, 7, and 8, the Office contends that Brennan teaches the production of a solid support comprising immobilized extendable oligonucleotides that represent every possible permutation of the 10-mer oligonucleotide (col. 9, Example 4, for example). Thus, the Office contends that the product of Brennan inherently contains oligonucleotides that possess 100% identity or homology to 10-mer segments of SEQ ID NOS: 1 and 4, as well as oligonucleotides that are perfectly complementary to 10-mer segments of SEQ ID NOS: 1 and 4, *i.e.*, options C and D of the claimed invention. Thus, the Office concluded that Brennan anticipates the claimed invention. Office Action at 6.

With regard to claim 5, the Office contends that each primer, SEQ ID NO: 17 or 18, necessarily comprises a 10-mer that was present in the product according to Brennan.

With regard to claim 6, the Office contends that an 8-mer plus nucleotide segment present in both *Mycobacterium tuberculosis* and *Mycobacterium africanum* would meet the claimed limitations. A BLAST search of a known sequence within the *Mycobacterium africanum* genome (Accession Number L26330) allegedly revealed a homologous segment within the *Mycobacterium tuberculosis* genome. The Office concluded there are inherently several 10-mer segments, present in both of the above genomes, that were present in the product according to Brennan. Office Action at 6.

This ground for rejection is respectfully traversed and reconsideration is requested for the following reasons.

U.S. 5,474,796 discloses an array of oligonucleotides, each composed of 10 nucleotides. These 10 mers are fixed on a support and ordered such that the sequence is identical to the previous element in nucleotide sequence, except that it deletes the 5' nucleotide, and adds a new 3' nucleotide. This document thus discloses a device composed of ordered nucleotides, which makes it possible to determine the sequence of a DNA fragment based on a particular hybridization pattern. The teachings of this document thus belong to DNA sequencing domain and not to a specific *M. tuberculosis* detection domain.

The cited art does not disclose a specific oligonucleotide sequence, but instead degenerate oligonucleotides. Thus, a nucleic acid according to point c) or d) of pending claim I was not disclosed regarding the complexity of the oligonucleotide mix described in these two documents.

Accordingly, Applicants respectfully submit that the pending claims are allowable over the cited references.

Claims 1-3 and 5-8 were rejected under 35 U.S.C. § 102(b) as being anticipated by New England Biolabs 1998/99 Catalog (NEB Catalog). The rejection of claim 6 is further evidenced by GENBANK Accession Number L26330 (uploaded to NCBI June 4, 1994) and BLAST search completed @ NCBI on August 13, 2008. Office Action at 6-7. With regard to claims 1-3, 7, and 8, the Office contends that page 121 of the NEB Catalog discloses a packaged product for sale (catalog #1255) comprising Random Primer 24. According to the Office, this product comprises every possible primer of 24 bases in length, and therefore, inherently anticipates the claimed invention. *Id.*

This ground for rejection is also traversed and reconsideration is requested for the following reasons.

New England Biolabs 1998/99 Catalog.

The oligonucleotids of the NEB catalog are random primers that hybridize to DNA random sites and that are used for the DNA synthesis by Klenow fragment of the *E. coli* DNA polymerase 1. The random primer 24, comprises 2.8×10^{14} different molecules. The random primer 24 is thus a complex mix of 24 mers. According to the catalog note, the random primer can serve as a universal primer for the DNA synthesis from a single-stranded matrix and as a universal hybridization probe.

In Rothstein *et al.* PNAS 1994, cited in the catalog, and more precisely page 4156, left column, it is stated that the 36 mers of NEB are used to improve the detection of the fragmented DNA of apoptotic cells. Low stringency conditions show that the oligonucleotides are not used to specifically detect a specific sequence, but to nonspecifically detect DNA. This document thus concerns random primer for methods (synthesis of a probe and universal DNA detection) different from the specific *M.*

tuberculosis detection and discrimination method of the present invention. The primers of the NEB catalog are used in low stringency conditions. Nothing indicates that these primers would be able to hybridize to SEQ ID NO: 1 and SEQ ID NO:4 in high stringency conditions.

Thus, this ground for rejection may also be withdrawn.

Allowable Subject Matter

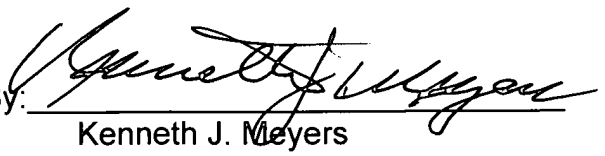
With regard to claim 4, the Office indicated that a search of the prior art revealed no reference teaching or fairly suggesting the oligonucleotide sequences recited in SEQ ID NOs: 17 and 18. This claim was objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 4 has been cancelled and rewritten in independent form as claim 5. Accordingly, claim 5 should be allowable.

If there are any additional fees due in connection with the filing of this Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: December 23, 2008

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